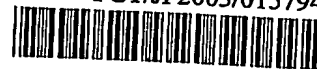


538,061
Translation

PATENT COOPERATION TREATY

PCT

PCT/JP2003/015794



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference A31654M	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/015794	International filing date (day/month/year) 10 December 2003 (10.12.2003)	Priority date (day/month/year) 10 December 2002 (10.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 45/06, 31/138, 31/167, 31/495, A61P 1/02, 23/02, 43/00		
Applicant SHOWA YAKUHHN KAKO CO., LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 10 December 2003 (10.12.2003)	Date of completion of this report 02 July 2004 (02.07.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed
- ☐ the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the claims:
 pages _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language _____ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 6, 7	YES
	Claims	1, 3-5	NO
Inventive step (IS)	Claims	2, 6, 7	YES
	Claims	1, 3-5	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims		NO

2. Citations and explanations

Document 1: JP 11-228398 A (Hisamitsu Pharmaceutical Co., Ltd.), 24 August 1999

Document 2: JP 7-291856 A (Yutoku Pharnaceutical Ind. Co., Ltd.), 7 November 1995

Document 3: JP 3-291221 A (Otsuka Pharmaceutical Factory, Inc.), 20 December 1991

Document 4: Journal of the American Pharmaceutical Association (1912-1977), 1954, Vol. 43, pp. 263-266 (abstract); CAlus Accession No. 1954:47432

Document 5: WO 02/055107 A1 (Showa Yakuhin Kako Co., Ltd.), 18 July 2002

Document 6: WO 97/07794 A1 (Showa Yakuhin Kako Co., Ltd.), 6 March 1997 & EP 858803 A1

Claims 1 and 3-5

The inventions set forth in claims 1 and 3-5 are not novel and do not involve an inventive step in the light of documents 1-3, cited in the international search report.

Documents 1-3 disclose medicinal compositions which include a local anaesthetic such as lidocaine and an antihistamine such as diphenhydramine, and substantially do not contain catecholamines. These documents 1-3 do not mention incorporation in the compositions of an "agent

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which sustains the anaesthetic effect"; however, the constituent which the applicant terms an "agent which sustains the anaesthetic effect" is no different as a substance from an "antihistamine", and the inventions set forth in claims 1 and 3-5 and the inventions disclosed in documents 1-3 are substantially indistinguishable as substances.

Claims 2, 6 and 7

The inventions set forth in claims 2, 6 and 7 are novel and involve an inventive step relative to documents 1-3, documents 4 and 5, cited in the international search report, and document 6, which is a patent family cited in the international search report.

None of documents 1-6 discloses or suggests an invention of a composition for surgery of the oral cavity or for dental use, or an invention of application as an "agent which sustains the action of a local anaesthetic".